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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,739	11/18/2003	Murugan R. Pandian	A-1789div	6774

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Donald E. Stout
Stout, Uxa, Buyan & Mullins, LLP
Suite 300
4 Venture
Irvine, CA 92618

EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,739	PANDIAN ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 18, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 6 lines 15-25 in the specification. The applicant discloses ITA is similar, to C5hCG, which is a nicked h-hCG obtained from a choriocarcinoma patient. ITA as defined, also includes fragments of ITA, or variants of ITA. Applicant does not disclose what fragments of ITA or what variants of ITA. Further, applicant does not disclose how these variants are varied. Furthermore applicant does not disclose what is nicked. There is no description in the specification disclosing what is nicked, how the variants are varied or what the fragments are. One of ordinary skill in the art would not know where a molecule binds if it is not disclosed where a molecule is varied or nicked.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is vague and indefinite because of the use of acronyms: i.e. ITA and hCG. Although the terms may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance.

Claim 23, line 6 the recitation "comparing the amounts of ITA and hCG" there is insufficient antecedent basis for this limitation.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step to determine the amounts of ITA and hCG. The instantly recited claims only require contacting antibodies that bind ITA and hCG. It is unclear how one can compare amounts of ITA and hCG if the amounts have not been determined.

Claim 23 step (c) "higher amount" is vague and indefinite. It is unclear what is considered to be a higher amount. There is no definition or guidance provided for the term in the specification. Is one decimal point above the standard considered higher? Are two standard deviations above the standard considered higher or is 10%, 20% or 22% above the standard considered to be higher? Please clarify.

Conclusion

4. No claims are allowed.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

O'Connor et al., (WO 00/70094) teaches diagnosis of gestational trophoblast disease (p. 54). O'Connor teaches that in gestational trophoblast disease including choriocarcinoma or hydatidiform mole, the ratio of B152/B109 is initially higher than found in normal pregnancy, but does not diminish during the course of the apparent pregnancy (p. 54 – p. 55).

O'Connor et al., (US 6,500,627) discloses a method for detecting gestational trophoblast disease. O'Connor discloses that a continuing high ratio of early pregnancy associated molecular isoform of hCG to late pregnancy associated molecular isoform of hCG in the sample indicates the presence of gestational trophoblast disease (col 4., lines 19-46).

Cole et al., Utility of Commonly Used Commercial human chorionic gonadotropin Immunoassays in the Diagnosis and Management of Trophoblastic Diseases, Clinical Chemistry 47:2 308-315 (2001). Cole et al discloses assays for monitoring patients with trophoblast disease (p. 309).

Cole (Immunoassay of human chorionic gonadotropin, its free subunits, and metabolites, Clinical Chemistry 43:12 2233-2243 (1997). Cole teaches immunoassays of hCG and also teaches that serum or urine containing entirely nicked hCG or free Beta and urine samples containing only Beta-core fragment have been found in certain trophoblast diseases cases (p. 2235).

Birken et al., (WO 00/61638) teaches two-site immunometirc assays using antibodies designated B151 and B152. Birken et al teach detection of hCG isoforms for use in the diagnosis of certain malignancies (p. 7).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary W. Counts
Examiner
Art Unit 1641
April 26, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/26/04